Remarks

Applicant has noted the various well-ordered, constructive comments set forth by the Examiner in the first Office Action and has modified the specification (and drawings) or otherwise responded to such comments as deemed appropriate.

The Examiner has inquired into the appropriateness of including, within the Field of the Invention, the dispensing of granulated solids "since the disclosed principles relate to fluidics." In response, Applicant wishes to point out that finely granulated solids are capable of flowing and may demonstrate properties like those of a liquid. Like a liquid, a granulated solid can be drawn through a conduit from one enclosure to another in the presence of a pressure differential. Also like a liquid, a granulated solid may be injected or dispensed. Referring in particular to Figure 4, Applicant contends that a finely granulated solid may be drawn into the pump (28) when the bellows (202) is expanded and may be forced out the outlet (220) when the bellows contract. A granulated solid in a liquid,such as a suspension, also naturally comprises a dispensable medication within the scope of the invention. In this regard, Applicant points to column 5, line 19 of U.S.Patent No. 4,146,029 (by Ellinwood) which discusses a medication dispensing apparatus "directed to powdered, liquid, suspension, or other dispensable form."

Applicant agrees that the present infusion system may be particularly significant in dispensing liquid medication; however, Applicant also recognizes the significance of dispensing finely granularized solid medicaments which flow.

To clarify the electronics section represented by numeral 30, Applicant has amended the drawings to indicate that element 30 is not a dividing line, but includes the battery 32 and the area above the detector 35 in Figure 2 and in front of the pump 28 in Figure 3.

Dual leads in Figure 5 have been changed to single lead lines from element 318 to 328; and 328 to 330. Directional arrows and a numeral designation for the key parameters element have also been added.

Regarding the Examiner's comment concerning the implantation of a carbon insert in the skull, Applicant notes that the Examiner's interpretation that the refill injection site may be remote is correct. That is, while the pump and electronics may be implanted in the torso, the fill/refill site may be at another location. The skull was selected only as an example. It should be noted, however, that the skull has been used for intracranial pressure monitor implants and that vitreous carbon has been placed in the body without problems. The use of vitreous carbon in the skull represents a proven and safe but nonobvious extension of prior art and experience. Applicant further points out that the insert in the skull is an alternative to the primary embodiment in which the antechamber and reservoir are encased in a single element that is preferably implanted conveniently in the torso.

The Examiner has rejected claims 27-31 as obvious based on Lenzkes and Walters. Claim 27 has been cancelled and has, in effect, been replaced by claim 73 which includes more detailed recitation. Claim 73 includes power cell means (shown in Figure 5 as element 310 and discussed on page 11, line 8) and medication pumping means which neither Lenzkes nor Walters even suggest. An examination of Fig. 6 of Lenzkes shows that an AC-to-DC convertor is provided, not a power cell. An externally applied AC power signal must, therefore, always be present whenever the system is in use (column 2, line 21). In addition, in claim 28, the power cell means is further described as rechargeable which further distinguishes over the limits of Lenzkes and Walters.

It is also worth noting that claims 29-31 (which now depend from claim 73) provide for programmed infusion rate input limits, while Lenzkes and Walters program "stimulating pulse characteristics such as amplitudes, width, interpulse, periods...." (Lenzkes, column 1, line 64). According to the invention, the electrical pulses which cause pumping should be the same with each resultant medication decaying output pulse ideally being the same. The various programmed pulse characteristics of Lenzkes and Walters are both inapposite and unrelatable to the programmed infusion rate inputs. The programmed infusion rate inputs, discussed in the specification on page 12, line 9 et seq., relate to the number of medication pulses requested over time, the key concern being dosage. Lenzkes and Walters are concerned with tissue stimulation at a given time and are not particularly concerned with previous stimulation patterns or counts. The types of stimulation pulse characteristics set forth in the references cannot be readily applied to the operation of the claimed invention nor are the pacer parameters disclosed in the references directed to the same purpose as the programmed infusion rate inputs, namely preventing overdose.

The Examiner suggests an interesting analogy between "medicament" infusion by stimulating the heart and infusion by electromechanical means. This analogy, which may seem of merit in view of the above-mentioned Ellinwood patent that teaches the infusion of medication from a pump in response to detected heart characteristics, is not appropriate for several reasons in addition to those previously mentioned. In heart pacing the "pumping element,"the heart, is generally fixed in design. If the natural performance of the heart is less than optimal, electrical stimulation inputs alone can effect changes in heart pumping; pacing does not provide for altering pump structure to achieve a desired output. An electromechanical infusion apparatus can employ specially designed

pumping mechanisms and output structure to achieve desired dispensing features or characteristics with relatively simple electrical inputs.

The pacer (with a heart "pump") and the infusion apparatus with an electro-mechanical pump both may have electrical inputs and pump flow outputs. However, the analogy fails in that (1) the electrical inputs are irreconcilably different; (2) the functions of the inputs relative to the pump are different; (3) the stored program inputs differ; and (4) the nature of the problems addressed differ. The pacer is concerned with proper heart pumping at one particular time while the infusion apparatus is concerned with dosage over time or, as recited in claims 29-31, "programmed infusion rate" which must not exceed a "corresponding fixed rate limit."

Referring now to the Examiner's rejection of claims 27 and 37-38 based on Spencer in view of Lenzkes, Applicant wishes to point out that Spencer was published in June, 1978 and Lenzkes issued in April, 1973. Despite this 5-year period, Spencer comments that "implants will soon follow but remote programmability of units will be required before useful implants can be accomplished successfully." Spencer thus suggests that remote programmability is the problem which must be solved before an implant could be practical and that remote programmability did not exist at the time of Spencer.

Spencer predicts that "programming will be done in a manner similar to that used in modern pacemakers," that is, that "electromagnetic induction will be used to couple digital pulses into an implanted control circuit." However, although the mode of programming (namely, induction of digital pulses) is predicted, programming purposes and elements vital to an infusion system are omitted. As previously discussed, the problem of infusion overdose is of primary concern for any infusion system. The

pacemaker of Lenzkes (and Walters) has no reason to address overdose and Spencer does not consider the question at all. Different delivery rates and alarm means for indicating a "failure to deliver insulin at the preprogrammed rate" are provided by Spencer; however, there is no disclosure of any means which "disallows [the infusing of] more than a preprogrammed dosage" as recited in claim 37 of the present application. Spencer and Lenzkes fail to specifically disclose any safeguard which prevents overdose and are thus distinguishable from claims 37 and 38.

Claim 73 recites "power cell means" (defined as rechargeable in claim 28) which provides power used to activate the medication pumping means. This feature also distinguishes claims 73, 28, 37, and 38 from cited prior art.

Claim 38 is deserving of special discussion. There is no disclosure, prediction, or even suggestion in any prior art that medication stored in an implanted reservoir be maintained at a "pressure ... below the pressure of the living body." As discussed in the Background of the Invention, a key safety feature of the present invention is to prevent medication from leaking out from the implanted device into the body. By maintaining the reservoir pressure negative relative to ambient body pressure, body fluid will leak into the implant rather than medication leaking out into the body. Spencer briefly mentions refilling a reservoir which expands while a freon-type gas in an outer chamber compresses. However, relative pressure between the reservoir and the human body is not discussed. In fact, other prior art (Blackshear in U.S.Patent No. 3,731,681 cited by the Examiner) teaches away from the relatively-negative pressure in the reservoir of the present invention. In Blackshear, a volatile fluid in a first chamber exerts pressure on a dividing means to force medication from a second chamber into the body. In doing so, "the outer [first] pump chamber ...

exerts a vapor pressure of greater than one atmosphere ... "(column 3, line 35). Similarly, Haerton (also cited by the Examiner) "maintains the liquid present in the supply reservoir constantly at a pressure in excess of the pressure at the point at which the liquid is discharged ...." (column 2, line 32). The prior art not only ignores the danger of possible leakage but, more noteworthy, adds to the problem by storing medication in the reservoir at artificially high pressures. Any leak would result in greater volumes of medication entering the body at greater rates. By including means for maintaining reservoir pressure below body pressure, claim 38 not only distinguishes over but greatly improves upon and adds an important measure of safety over the prior technology.

The Examiner has rejected claims 39 and 40 under 35 U.S.C. 103 as obvious, citing Spencer, Lenzkes, and Crone. The essence of those cancelled claims is now found in claims 76-78. The above nonobviousness arguments pertaining to claims 73, 37, and 38 would similarly apply to newly inserted claims 76, 77 and 78 which embody the inventive concepts of cancelled claims 39 and 40 as a novel method. Claims 77 and 78 include a feature which provides for an alarm signal when pressure in the reservoir reaches a threshold which is greater than a normal level but less than ambient body pressure. By properly setting the threshold (for example, -1 psig as stated in the specification on page 4, line 27) leakage can be detected shortly after it occurs.

Claims 38, 76, 77 and 78 underscore the novel redundant safety features embodied in the invention, which suggests the patentability of these claims. The apparatus of claim 38 and the methods of claims 76-78 show that leakage out is greatly impeded by the pressure differential and that, if leakage does occur, an alarm will activate at an appropriate time. Where none of the cited references even contemplate negative reservoir

pressure and none disclose such redundant safety measures, Applicant contends that the rejection of these claims would not be proper.

Further, with regard to the rejection of claims 38 and 76-78, Applicant further wishes to point out that the present invention, although usable external to the body (FIELD OF INVENTION, line 10), is also implantable. Crone, as the Examiner indicates, is only for external use. This difference in potential environments is significant. Crone has no need for and does not disclose features of patient-unit remote and direct intercommunication; is not concerned with leakage; and is not concerned with the level of pressure in its external medication reservoir. These features which form the basis of claims 38 and 76-78 are absent from Crone. A review of Spencer, (which does consider an implantable unit) similarly fails to do more than predict the "remote programmability of an infusion system" even though external programming like Crone was in the prior art at the time. Reading Spencer in view of Crone and Lenzkes, one can conclude that in 1978 remote programmability was viewed as a need for future systems (Spencer) notwithstanding the fact that pacemakers were programmed (Spencer, Lenzkes) and external infusion systems had program inputs (Crone). Where remote programming for internal infusion systems in general was not taught with enabling disclosure by the cited references, Applicant submits that the subject matter of the claims is even moreso untaught and unsuggested and non-obvious in view of the cited art.

Referring to the section 103 rejections relating to claims 56-61, Applicant points out that claim 56 has been redrafted as independent claim 79. Applicant contends that claim 79 is patentably distinguishable over Spencer in view of Crone (and Blackshear) in that no cited prior art "disallows pumping... when pumping commands exceed a preset limit." As discussed in the specification

and illustrated in the drawings, there are several elements which contribute to this effect. Rate limit control elements 324 and 326 prevent electrical pulse inputs to the coil 204 (see Figure 5) when programmed requests exceed a preset dose rate limit. Elements 324 and 326 provide a hardwired, safe dosage limit; Spencer, Crone, and Blackshear do not. Spencer provides programmed rate inputs, a feedback loop to insure constant infusion-delivery rates," and "an alarm if the pump fails to deliver insulin at the programmed rate." Crone provides a plurality of sequential infusion regimen, a presettable infusion duration, a "check sum" (the meaning of which is not clear), a volume infused indicator, and various control instructions such as "continue last infusion." Blackshear teaches nothing about the inhibiting of pumping. According to the cited Spencer and Crone references if a programmed input requested more than a safe dose of medication (1) an alarm might sound (if the alarm in Spencer were adapted to indicated overdose requests); (2) the overdose would be measured as it was infused or may even be prolonged by a "continue last infusion" command; or (3) the unsafe condition would occur unnoticed. Applicant realizes that Spencer and Crone take measures to assure that inputs are proper, e.g., Spencer employs a redundant pulse code. Applicant also avoids improper input commands. However, if an improper input is entered, only the present invention prevents pumping and overdose injection by including hardwired limit control elements. Applicant views the distinction as one which might bear on a patient's life or death. Accordingly, Applicant contends that the inclusion of these fatality-preventing elements -- which certainly would not have been omitted were they known, apparent, or obvious -- supports the patentability of claim 79 and the claims 57-61 which depend therefrom.

Regarding claims 79 -82, Applicant wishes to point out that these inserted claims are notably directed to implanted, implantable, and external devices. These claims are suggested by line 10 in the FIELD OF THE INVENTION which states that the invention, although principally an implantable device, "could also be used external to a living being for the infusion of medication." Claim 79 emphasizes the continuous, RC decay infusion flow of medication into the body which better simulates normal body functioning and is discussed in the DESCRIPTION OF THE INVENTION on page 8, line 22, et seq.

Claim 83 is supported at page 6, line 4 and line 11 of the DESCRIPTION OF THE INVENTION.

Claim 84 is supported at page 18, line 28 of the DESCRIPTION OF THE INVENTION.

Applicant respectfully submits that all rejections and objections have been traversed or overcome by amendment or argument and that the application is now in condition for early allowance.

Copies of the following patents cited previously by Applicant are included herein for the convenience of the Examiner. Although some of the references are not prior art, they are included and discussed to show the current trends as well as the state-of-the-art.

U.S.Patent No.	Inventors	Issue Date
3,527,220	G. D. Summers	Sep. 8, 1970
3,894,538	G. Richter	July 15, 1975
3,951,147	Tucker et al	Apr. 20, 1976
4,003,379	E. H. Ellinwood, Jr.	Jan. 18, 1977
4,126,132	Portner et al	Nov. 21, 1978
4,140,131	Dutcher et al	Feb. 20, 1979
4,146,029	E. H. Ellinwood, Jr.	Mar. 27, 1979
4,193,397	Tucker et al	Mar. 18, 1980
4,221,219	E. M. Tucker	Sep. 9, 1980

Summers, which discloses an implantable drug administrator activated by a rotating magnet is not programmable; employs a peristaltic pump; has no command receiver; and does not include the various safety features of the present invention, such as a negative pressure reservoir, a rate limit control element, and alarm signal elements. Richter discloses an implanted drug dispensing device having an outlet tube closed off by a porous plug. However, it does not consider negative reservoir pressure, back-up safety (including valves, subcutaneous alarm, dosage limits), and programmability. Further, Richter relies on osmotic pressure to produce infusion rather than commands to a pump. The Tucker patents teach implanted infusate bellows pumps without discussion of programmability, negative reservoir pressure rate limit control, subcutaneous alarm, or patient infusion requesting. Portner discloses an external device having a pump with two-limit stops, but fails to use the stops to control pumping as in the present invention. Portner discusses alarms, power supplies, and control electronics but all in an external, intraveneous system. Being external, the Portner system features apparatus not directed to implant safety. No leakage, no negative reservoir pressure, no refillability, no body compatibility, no command receiving or patient-unit interaction, and no controlled decaying output flow is suggested as in the present invention. Lastly, Dutcher considers subcutaneous signalling but only in a pacemaker context where electrical stimulation to the heart is the normal output. In Dutcher, an electrical stimulation to "another portion of the body" is applied as a warning that there is a pending failure or failure of the pacemaker. The present invention provides a subcutaneous signal where there is otherwise no electrical stimulation unlike Dutcher where the invention is directed to electrical stimulation as its essential object. In Dutcher subcutaneous alarm is a straightforward extension whereas the subcutaneous alarm in the infusion environ-

ment is totally unrelated to any infusion object. Further, the present invention generates alarms in response to vital, distinguishable conditions (leakage, proper infusion delivery and the like) not considered by Dutcher. The previously discussed Ellinwood patent, which is directed to only closed loop operation, similarly fails to contemplate the patient interaction and various safety features embodied in the invention.

It should finally be noted that the references cited by the Examiner and Applicant do not teach an essentially continuous, RC infusion as claimed by the invention.

The above patents and those discussed in the application and this response support Applicant's contention that the prior technology and current trends fail to suggest the claimed invention and underscore its technical significance.

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